

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND
INTERFERENCES

Appl. No.	:	10/542,506
Applicant	:	John L. Holahan
Filed	:	July 15, 2005
Title	:	Improved Thickened Beverages For Dysphagia
TC/A.U.	:	1618
Examiner	:	D. L. Jones
Conf. No.	:	5924
Docket No.	:	SITH 9317W1

Mail Stop APPEAL BRIEF - PATENTS
Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPELLANT'S BRIEF (37 C.F.R. § 41.37)

This brief is in furtherance of the Notice of Appeal filed in this case on April 29, 2010. A two-month extension of time is requested; the fee for a one-month extension has already been paid in connection with the filing of Amendment H after Appeal, amending the specification but not the claims.

The fees required under § 41.20(b)(2) and any required petition for extension of time for filing this brief and fees therefor are submitted herewith.

This brief contains these items under the following headings and in the order set forth below (37 C.F.R. § 41.37(c)(1)):

- I. REAL PARTY IN INTEREST
- II. RELATED APPEALS AND INTERFERENCES

- III. STATUS OF CLAIMS
- IV. STATUS OF AMENDMENTS
- V. SUMMARY OF CLAIMED SUBJECT MATTER
- VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL
- VII. ARGUMENT
- VIII. CLAIMS APPENDIX
- IX. EVIDENCE APPENDIX
- X. RELATED PROCEEDINGS APPENDIX

I. REAL PARTY IN INTEREST (37 C.F.R. § 41.37(c)(1)(i))

Simply Thick, LLC.

II. RELATED APPEALS AND INTERFERENCES (37 C.F.R. § 41.37(c)(1)(ii)))

None.

III. STATUS OF CLAIMS (37 C.F.R. § 41.37(c)(1)(iii))

A. TOTAL NUMBER OF CLAIMS IN APPLICATION

Claims in the application are: 89

B. STATUS OF ALL THE CLAIMS

1. Claims cancelled: 1-38 and 46-56
2. Claims withdrawn from consideration but not cancelled: 57-89
3. Claims pending: 39-45
4. Claims allowed: NONE
5. Claims rejected: 39-45

C. CLAIMS ON APPEAL

The claims on appeal are: Claims 39-45.

IV. STATUS OF AMENDMENTS (37 C.F.R. § 41.37(c)(1)(iv))

No amendments to the claims have been entered by the Examiner since the Final Rejection dated February 2, 2010.¹

¹ Appellant filed its Amendment D After Final on April 29, 2010 in response to the Office communication (final rejection) dated February 2, 2010. The Examiner issued an Advisory Action dated May 13, 2010 denying entry of Amendment D After Final because "the claims do not simplify issues of record" and because "[a]dditional searching and consideration is necessary."

In response to the May 13, 2010 Advisory Action, Appellant, on May 20, 2010, filed its Amendment E under 37 CFR 41.33 After Appeal to comply with requirements of form expressly set forth in the February 2, 2010 final rejection and to present rejected claims in better form for consideration on appeal. In an Advisory Action mailed June 11, 2010, the Examiner denied entry of Amendment E because "[t]he proposed amendment contains claim limitations that were not examined by the Examiner."

In response to the June 13, 2010 Advisory Action, Appellant, on June 17, 2010, filed its Amendment F under 37 CFR 41.33 After Appeal to comply with requirements of form expressly set forth in the February 2, 2010 final rejection. Specifically, Appellant amended paragraph [0077] to remove an imbedded hyperlink as required by the Examiner and responded to the Examiner's Request for Information under 37 CFR § 1.105. Claims 39 and 42 were amended to recite a "thickener concentrate" consistent with original claims 40, 41, and 44. Claims 44 and 45 were amended to depend from Claim 43 rather than Claim 42, as those claims did not properly limit Claim 42. On June 24, 2010, the Examiner issued an Advisory Action, refusing entry of Amendment F because amendment F raises new issues that would require further consideration and/or search and "[t]he rejections of record are maintained for reasons fo [sic] record in the final rejection 2/2/10." Appellant stands ready to accept any and all of the amendments in Amendment F should the Board find that they place the case in condition for allowance. 37 CFR 41.50.

On July 1, 2010, Appellant's representatives J. Philip Polster and Steve Balsarotti had a brief telephone conversation with the Examiner, in which the Examiner indicated that she would enter an amendment that included an amendment of the specification to remove an active hyperlink and a response to the Rule 105 Request for Information made by the Examiner in the Office communication (final rejection) dated February 2, 2010, provided Appellant did not include any claim amendments. Appellant has subsequently filed Amendments G and H attempting to comply with that requirement and not amending the claims. Amendment H has now been entered.

Thus, the claims listed in Section VIII and discussed in Sections V and VII are those presented in Amendment C, filed on November 23, 2009.

**V. SUMMARY OF THE CLAIMED SUBJECT MATTER (37 C.F.R.
§ 41.37(c)(1)(v))**

The claimed invention is particularly described in the Specification at paragraphs [0016], [0020]-[0022], and [0050]-[0078].²

Claim 39 is the only independent claim in this appeal. Claim 39 calls for a process for the production of homogenous single phase thickened beverages ([¶[0078]]) suitable for consumption by a person suffering from dysphagia ([¶[0062]]), the process comprising connecting a source of aqueous liquid thickener (ref. no. 24, Fig. 2; ref. no. 33, Fig. 3; ¶¶ [0021]-[0022]; ¶ [0052]; ¶ [0059]) to a dispensing machine (ref. nos. 10-11, 12-14, Fig. 1; ref. nos. 20-21, 25-27, Fig. 2; ref. nos. 30-31, 34-36, Fig. 3; ¶ [0050], ¶ [0053]) that is capable of dispensing non-thickened beverages (¶¶ [0021]-[0022]; ¶¶ [0050], ¶ [0051]).

Dependent claims 40 and 41 set out that the dispensing machine includes a container of thickener concentrate (ref. no. 24, Fig. 2; ref. no. 33, Fig. 3; ¶¶ [0021]-[0022]; ¶ [0052]; ¶ [0059]), a switch (¶ [0050]; ¶ [0060]) which selectively controls whether or not the thickener concentrate is included in the beverage, and a metering pump (ref. no. 23, Fig. 2; ref. no. 32, Fig. 3). The dispensing machine is designed such that beverages exit the dispenser at the correct thickness with a homogenous appearance and are ready to drink, whether or not the beverage thickness is increased by inclusion of the thickener concentrate ([¶[0078]]). In accordance with claim 40, an in-line static mixer (ref. no. 22, Fig. 2;

² Paragraph numbers herein are those of the application as filed. The paragraph numbers of the published application are increased by one number from those in the application as filed.

¶ [0021]; ¶ [0067]; ¶¶ [0070-0071]) is connected to the container of thickener concentrate. In accordance with claim 41, the dispensing machine includes an exit nozzle (ref. no. 31, Fig. 3) which produces mixing.

Dependent claims 42-45 set out that the thickener concentrate (ref. no. 24, Fig. 2; ref. no. 33, Fig. 3; ¶¶ [0021]-[0022]; ¶ [0052]; ¶ [0059]) comprises at least one soluble food fiber thickener selected from the group consisting of sodium alginate, potassium alginate, ammonium alginate, carrageenan, sodium carboxymethylcellulose, hydroxypropyl cellulose, hydroxypropyl methyl cellulose, locust bean gum, guar gum, and or xanthan gum (¶ [0030]). The thickener is between 1% and 10% by weight of the thickener concentrate (¶ [0053]) and between 0.3% and 1% by weight of the beverage (¶ [0029]).

**VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL (37 C.F.R.
§ 41.37(c)(1)(vi))**

The issues on appeal are:

1. Whether Claims 39-45, all of the claims under examination, are properly rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.
2. Whether Claims 39-45, all of the claims under examination, are properly rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Appellant regards as the invention.
3. Whether Claims 39-41 are anticipated by Wierlo, U.S. Patent 3,839,407 ("Wierlo") under 35 U.S.C. § 102(b).
4. Whether Claims 39-45, all of the claims under examination, are obvious under 35 U.S.C. § 103(a) over Applicant's Admission in view of *Wierlo* in further view of Uzuhashi et al, U.S. Patent No. 6,455,090 ("Uzuhash").

VII. ARGUMENT (37 C.F.R. § 41.37(c)(1)(vii))

A. Background

The present invention relates to alleviation of longstanding major problems in the treatment of common, serious, potentially life-threatening swallowing problems known collectively as "dysphagia." Patients suffering from dysphagia are prone to having foodstuffs and beverages go into their lungs rather than being routed properly to their stomach.

Treatment of patients with dysphagia is a particular concern in such facilities as nursing homes and hospitals. It has long been known that an effective treatment for dysphagia is feeding patients liquid foods and beverages which have been thickened to a consistency suitable for consumption by the patient. (Specification ¶ [0004]).

More than a year before the filing date of the present application, Appellant sold individual foil packets of aqueous concentrate thickener, consisting essentially of water and completely hydrated xanthan gum; each packet was sized to be opened and stirred or shaken into a single serving of liquid food or beverage, giving the food or beverage a thickness suitable for consumption by a patient suffering from dysphagia. The Examiner refers to the sale and use of Appellant's packets of aqueous concentrate thickener as "Applicant's Admission."

This process and these packets are described in Appellant's U.S. Patent No. 7,638,150. Neither the PCT application nor the U.S. application for this

patent was published before the filing date of the present application and neither they nor the patent is prior art with respect to it.

The present invention comprises a process for the production of homogeneously stable single phase thickened beverages suitable for consumption by a patient suffering from dysphagia, the process comprising connecting a source of aqueous liquid thickener to a dispensing machine that is capable of dispensing non-thickened beverages.

Preferably, the dispensing machine can change over from producing thickened to un-thickened foods at the touch of a switch. Appellant's unique process includes the use of a thickener concentrate which facilitates in-line mixing and preparation of thickened beverages in a beverage dispenser or container. Such a process can also include a metering device and an in-line mixing system to dispense thickened beverages.

Dispensing systems are a common means of preparing beverages in institutions. They provide a quick and convenient way to prepare large quantities of multiple beverages from the same piece of equipment without a lot of walking around and without numerous containers. Until the present invention, thickened beverages required separate handling and separate preparation. Often, an additional person is required, just performing the task of thickening. The present invention allows preparation of all the facility's beverages, un-thickened or thickened, from the same machine from the same concentrates. This is a tremendous labor and convenience benefit to the operation of the facility.

B. Responses to the Rejections

1A. The rejection of Claims 39-45 under 35 U.S.C. § 112, first paragraph.

Claims 39-45 have been rejected under 35 U.S.C. § 112, first paragraph:

as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

(February 2, 2010 Final Office Action, p. 5).

Specifically, with respect to Claims 39-45, the Examiner stated:

Independent claim 39 has been amended to read "aqueous liquid thickener". However, review of the specification indicates that reference is made to an "aqueous liquid" (see paragraph [0079]), an "aqueous based beverage" (see paragraph [0016]), and a "liquid aqueous food" (see paragraph [0029]), not an "aqueous liquid thickener". Thus, the phrase is believed to be new matter which is not supported by the specification.

(February 2, 2010 Final Office Action, p. 5-6).

The Examiner further stated that "As a result of the claims being amended to contain new matter, written description would also be lacking since the instant application does not sufficiently describe the invention as it relates to the aqueous liquid thickener." (February 2, 2010 Final Office Action, p. 6).

Appellant submits that those skilled in the art would instantly recognize that the term "aqueous liquid thickener" means a thickener having a liquid water base. In the context of claim 39, the thickener in the aqueous water base must be of such a concentration that when it is mixed with a non-thickened beverage it thickens the beverage sufficiently to be suitable for consumption by a person

suffering from dysphagia. Such an aqueous liquid thickener is described throughout the Specification. For example, at ¶[0054] a method of making a thickener concentrate suitable for use in a dispenser is described: "In an aspect, a sufficient quantity of thickener powder for the concentrate thickener being prepared is admixed with water in a suitable mixing vessel."

An objective standard for determining compliance with the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989); MPEP § 2163.02. "In order to satisfy the written description requirement, the disclosure as originally filed does not have to provide *in haec verba* support for the claimed subject matter at issue." *Purdue Pharma LP v. Faulding Inc.*, 230 F. 3d 1320 (Fed. Cir. 2000). The disclosure of the present application clearly indicates that appellant was in possession of the invention as claimed at the time the application was filed, and clearly provides support for the questioned language.

Appellant is more than willing to amend claim 39 to replace "liquid aqueous thickener" with "thickener concentrate" so as to be consistent with its dependent claims: claims 40 and 41 ("A process in accordance with Claim 39 wherein the dispensing machine includes a container of thickener concentrate..."), and claim 44 ("A process in accordance with Claim 42 where the xanthan gum is between 1% and 10% of the thickener concentrate." [Claim 42 is dependent on Claim 39]). This "thickener concentrate" language has been in these claims since the application was filed. However, in the context of claim 39,

it is respectfully submitted that the phrase "liquid aqueous thickener" would be plainly understood by those skilled in the art to mean a water-based liquid thickener concentrate containing sufficient thickener that when it is added to a beverage it makes the beverage suitable for consumption by a person suffering from dysphagia.

1B. The rejection of Claims 44 and 45 under 35 U.S.C. § 112, first paragraph

In the February 2, 2010 Final Office Action, the Examiner rejected Claims 44 and 45 under 35 U.S.C. § 112, first paragraph, because "[t]he claims contain new matter because review of the specification does not set forth (*sic.*) the ranges appearing in the claims as amended." The Examiner further asserted that "Applicant is reminded that one cannot neither arbitrarily select endpoints from a range disclosed in the specification nor create a range." (February 2, 2010 Final Office Action, p. 6). The Examiner provided no citation of authority for this proposition of law, which Appellant respectfully asserts is incorrect. See *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1566 (Fed.Cir.1991) ("ranges found in applicant's claims need not correspond exactly to those disclosed in [the specification]; issue is whether one skilled in the art could derive the claimed ranges from the ... disclosure.").

As discussed more fully below, the range limitations in Claims 44 and 45 are more specific, and narrower than those disclosed in the specification. Thus, one skilled in the art could easily derive the claimed ranges from the specification of the instant application. Moreover, Claims 44 and 45 are merely claiming less

than what is disclosed within the specification. Claims 44 and 45 thus comply with 35 U.S.C. § 112.

Claim 44

The Examiner stated "[s]pecifically, in claim 44, and endpoint of 1% is not disclosed in the specification." (February 2, 2010 Final Office Action, p. 6).

The Specification recites at ¶ [0053] that the concentration of thickener in the thickener concentrate is "between about 1 and about 10% thickener by weight." Claim 44 calls for "between 1% and 10% of the thickener concentrate." Thus, although the range claimed in Claim 44 is slightly narrowed by elimination of the word "about," it does not add new matter, and Claim 44 complies with the written description requirement of 35 U.S.C. § 112, first paragraph.

Claim 45

The Examiner asserts that "the range 0.3% and 1% of the beverage are not set forth in the disclosure." (February 2, 2010 Final Office Action, p. 6). However, the disclosure does provide support for the claimed range: "The thickener comprises xanthan gum whose concentration ranges from about 0.01% to about 5% by wt. of a final ready to drink liquid (water based) food and preferably from about 0.1% to about 2% of a final ready-to-consume liquid aqueous food." (¶ [0029]). Claim 45 was not amended in response to the art cited, and Appellant has not argued that the particular range set out in the claim produces an unexpected result. Thus, Claim 45 merely claims less than Appellant is entitled to claim. It is respectfully submitted that it complies with the

written description requirement of 35 U.S.C. § 112, first paragraph and does not include new matter.

2. The rejection of Claims 39-45 under 35 U.S.C. § 112, second paragraph.

Claims 39-45 have been rejected under 35 U.S.C. § 112, second paragraph "as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." (February 2, 2010 Final Office Action, p. 6).

Claim 39

Specifically, with respect to Claims 39-45, the Examiner stated:

The claims as written are ambiguous because independent claim 39 has been amended to read "a source of aqueous liquid thickener". However, it is unclear if Applicant is referring to an "aqueous liquid" (see specification paragraph [0079]), an "aqueous based beverage" (see specification paragraph [0016]), a "liquid aqueous food" (see specification paragraph [0029]), or the soluble food fiber thickeners of claim 42, for example. Please clarify so that one may readily ascertain what is being claimed.

(February 2, 2010 Final Office Action, p. 7).

As noted above, Appellant's attempts to clarify by making the terminology consistent with the dependent claims ("thickener concentrate") have been rebuffed by the Examiner. Nonetheless, there is nothing ambiguous about the phrase "aqueous liquid thickener." However, in the context of claim 39, it is respectfully submitted that the phrase "liquid aqueous thickener" would be plainly understood by those skilled in the art to mean a water-based liquid thickener concentrate containing sufficient thickener that when it is added to a beverage it

makes the beverage suitable for consumption by a person suffering from dysphagia.

The M.P.E.P. provides at § 2171:

Definiteness of claim language must be analyzed, not in a vacuum, but in light of:

(A)The content of the particular application disclosure;

(B)The teachings of the prior art; and

(C)The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.

(A) As indicated above in the discussion of the rejection of the claims under the first paragraph of 35 U.S.C. § 112, the application disclosure at ¶ [0054] describes the manufacture of a thickener concentrate suitable for use in a beverage dispenser as including mixing a powdered thickener with water. The specification of application Serial No. PCT/US02/24525, which is incorporated by reference into the instant specification at ¶ [0028], describes numerous examples of making an aqueous liquid thickener suitable for use in the process of claim 39.

(B) Likewise, the cited *Uzuhashi* patent discloses liquid thickeners in which the solvent is water.

(C) Finally, there is no reason to believe that those skilled in the art would read the claim language as anything other than the plain meaning of the words: what is connected to the dispenser is a source of a water-based liquid thickener concentrate containing sufficient thickener that when it is added to a beverage it

makes the beverage suitable for consumption by a person suffering from dysphagia.

Claim 41

With respect to Claim 41, the Examiner stated, "The claim as written is ambiguous because of the phrase 'sufficient pressure drop'. In particular, it is unclear what pressure drop is necessary in order to obtain the desired results."

Claim 41, on its face, spells out exactly what determines a "sufficient pressure drop." Claim 41 requires a sufficient pressure drop such "that beverages exit the dispenser at the correct thickness, with a homogenous appearance and are ready to drink, whether the beverage thickness is increased by inclusion of the thickener concentrate or not." The claim parrots language from the Specification at ¶ [0068] ("Typical nozzle designs that would work with this system have a high pressure drop or a narrow gap to pump through or both. The final beverage exits the nozzle as a ready-to-consume thickened beverage for a dysphagic patient."). Thus, when Claim 41 is interpreted in light of the application disclosure and the claim interpretation that would be given by one of ordinary skill in the art as required by MPEP § 2171, the language of Claim 41 is sufficiently definite.

3. The rejection of Claims 39-41 under 35 U.S.C. § 102(b).

Claims 39-41 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Wierlo (US Patent No. 3,839,407).

Wierlo discloses an apparatus for mixing thickened substances. The apparatus comprises a dispensing nozzle and a

combination agitator-mixer-scraper. In addition, Wierlo discloses that unflavored substances such as ice cream, milkshakes, slush, ice, or frozen custard flows toward and exit nozzle the substance comes in contact flavored syrup (see entire document, especially, abstract; column 1, lines 6-13; column 2, lines 15-18). In the detailed description of the drawings, the details of the apparatus disclose that the dispense machine comprises a compressor motor, various storage tank, and optionally, a pump (column 2, lines 24-46). Thus, both Applicant and Wierlo disclose a process for the production of a homogenous single phase thickened beverage."

(July 23, 2009 Office Action, p. 5) (emphasis in original). The Examiner maintained the same rejection in the final Office Action. (February 2, 2010 Final Office Action, p. 3), and, in response to Appellant's arguments, added:

The dispensing machine of Wierlo is selectively dispenses a thickened food (ice cream, frozen custard, milkshake, etc.) into the dispensing nozzle (abstract; column 3, lines 16-35). ... The dispensing machine has a switch mechanism to allow the operator to regulate the amount of food product being dispensed. Thus, both Applicant and Wierlo disclose a process for the production of a homogenous single phase thickened beverage comprising connecting a thickener to a dispensing machine and a switch mechanism for controlling the amount of thickener present.

The Examiner's description of *Wierlo*'s construction is generally accurate. However, *Wierlo* does not anticipate any of the claims.

The M.P.E.P. provides at § 2131:

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as contained in the claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Claim 39

Claim 39 calls for a process for the production of homogenous single phase thickened beverages *suitable for consumption by a person suffering from dysphagia*, the process comprising connecting a *source of aqueous liquid thickener* to a *dispensing machine that is capable of dispensing non-thickened beverages*. *Wierlo* has none of the italicized elements of the process.

Importantly, *Wierlo* does not produce a beverage “suitable for consumption by a person suffering from dysphagia” because, as set out in Appellant’s application, “[t]hickening the beverages of those humans afflicted with dysphagia is a common method of managing dysphagia. Thickening provides better bolus control, greater oral stimulation, and when swallowed, if incompletely propelled into the esophagus, it helps prevent undesired and potentially fatal aspiration of fluids into the lungs.” (¶ [0004]). One skilled in the art would recognize that a product that melts in the mouth will not maintain bolus control. Further, one skilled in the art would recognize that a beverage that changes thickness over time, i.e. as it melts, is not suitable for a person with dysphagia, who requires a specific thickness.

Appellant emphasizes that in the context of the specification and claim language the phrase “suitable for consumption by a person suffering from dysphagia” is a positive limitation, defining the physical characteristics of the beverage produced by the method of the invention. It is not merely an intended use for the beverage. The Examiner’s reliance on M.P.E.P. § 2111.02, Section II is misplaced. As recognized in that section,

[A] claim preamble has the import that the claim as a whole suggests for it." *Bell Communications Research, Inc. v. Vitalink Communications Corp.*, 55 F.3d 615, 620, 34 USPQ2d 1816, 1820 (Fed. Cir. 1995). "If the claim preamble, when read in the context of the entire claim, recites limitations of the claim, or, if the claim preamble is 'necessary to give life, meaning, and vitality' to the claim, then the claim preamble should be construed as if in the balance of the claim." *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165-66 (Fed. Cir. 1999). See also *Jansen v. Rexall Sundown, Inc.*, 342 F.3d 1329, 1333, 68 USPQ2d 1154, 1158 (Fed. Cir. 2003)(In considering the effect of the preamble in a claim directed to a method of treating or preventing pernicious anemia in humans by administering a certain vitamin preparation to "a human in need thereof," the court held that the claims' recitation of a patient or a human "in need" gives life and meaning to the preamble's statement of purpose.).

Wierlo does not connect "a source of aqueous liquid thickener" to a dispensing machine. *Wierlo* connects a source of unthickened liquid to a freezer in his dispenser, where he converts the liquid to a partially liquid, partially solid "ice cream, frozen custard, milkshakes, slush, ice, etc." (Col. 1, lines 14-18)

Wierlo does not connect anything to a dispenser "that is capable of dispensing non-thickened beverages." His dispenser is capable only of dispensing partially frozen beverages and foods.

For all of the foregoing reasons, *Wierlo* does not anticipate claim 39, or any of its dependent claims 40-45. Each of the dependent claims also adds limitations not found in *Wierlo*.

Claim 40

Claim 40 calls for a process in accordance with Claim 39 wherein the dispensing machine includes a *container of thickener concentrate*, a *switch which selectively controls whether or not the thickener concentrate is included in the*

beverage, and a metering pump and an in-line static mixer connected to the container of thickener concentrate and designed such that beverages exit the dispenser at the correct thickness, with a homogenous appearance and are ready to drink, whether the beverage thickness is increased by inclusion of the thickener concentrate or not.

Wierlo lacks at least all of the italicized elements of the process of claim 40. He does not have a container of thickener concentrate, he does not have a switch which selectively controls whether or not the thickener concentrate is included in the beverage, he does not have a metering pump, and he does not produce beverages which are ready to drink whether the beverage thickness is increased by the inclusion of the thickener concentrate or not.

Claim 41

Claim 41 calls for a process in accordance with Claim 39 wherein the dispensing machine includes a *container of thickener concentrate, a switch which selectively controls whether or not the thickener concentrate is included in the beverage, a metering pump, and an exit nozzle*, the exit nozzle producing a sufficient pressure drop that beverages exit the dispenser at the correct thickness, with a homogenous appearance and are *ready to drink, whether the beverage thickness is increased by inclusion of the thickener concentrate or not.*

Wierlo lacks at least all of the italicized elements of the process of claim 41. He does not have a container of thickener concentrate, he does not have a switch which selectively controls whether or not the thickener concentrate is included in the beverage, he does not have a metering pump, and he does not

produce beverages which are ready to drink whether the beverage thickness is increased by the inclusion of the thickener concentrate or not.

4. The rejection of Claims 39-45 under 35 U.S.C. 103(a).

Claims 39-45 have been rejected under 35 U.S.C. § 103(a) "as being unpatentable over Applicant's admission in view of Wierlo (US Patent No. 3,830,407) and in further view of Uzuhashi et al (US Patent No. 6,455,090)" (February 2, 2010 Final Office Action, p. 8):

It would have been obvious to one of ordinary skill in the art to generate a process for the production of a homogeneous thickened beverage comprising connecting a source of aqueous liquid thickener to a dispensing machine for the following reasons. (1) Applicant admits that packets the aqueous liquid thickener packages are known. Therefore, aqueous liquid thickeners are known in the art and were available to the public more than a year before the effective filing date of the present application. (2) It is well known in the art, as indicated by Wierlo, to have a thickened beverage (i.e., milkshake, frozen custard, ice cream, etc.) in contact (i.e., in connection with) with a dispensing machine. (3) Uzuhashi et al disclose motivation for one to use a dispensing machine. In particular, the document discloses that the viscosity and formulation of gels of food require that the gels be highly flexible commodities rather than uniform commodities.

(February 2, 2010 Final Office Action, pp. 10-11).

The short answer to this rejection is that there is no hint of a suggestion or teaching in Appellant's commercial individual packets of aqueous liquid thickener or in *Uzuhashi*, who discloses a somewhat similar individually packaged thickener, that these packets could somehow be connected to a beverage dispenser as called for in claim 39, nor is there any hint in *Wierlo* that his ice cream/milkshake machine could somehow be modified to attach a source of aqueous liquid thickener and dispense beverages suitable for consumption by a

person suffering from dysphagia as called for in that claim. The only suggestion of, or motivation for, such a combination is in Appellant's disclosure. The details set out in dependent claims 40-41 are not shown or suggested by any of the cited art. Although compositions corresponding to those set out in claims 42-45 were known at the time the application was filed, nothing in the prior art suggested their use in a beverage dispenser.

The longer answer follows.

Claim 39

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or non-obviousness, if any.

a. Determining the scope and contents of the prior art.

(1). Applicant's Admission

Appellant's assignee sold packets of aqueous thickener concentrate in accordance with the disclosure of its US Patent application 10/485,879 more than one year before the effective filing date of the instant invention. These were individual packets of thickener concentrate, intended to be mixed with a single

serving of liquid food or beverage, to make the food or beverage suitable for consumption by a person suffering from dysphagia. As indicated above, the application (now U.S. Patent No. 7,638,150) was published after the filing date of the present application and is not prior art with respect to it.

(2). Wierlo, US Patent No. 3,830,407

The scope and content of *Wierlo* is discussed above. It is a freezer/dispenser for ice cream, frozen custard, milkshakes, and the like.

(3). Uzuhashi et al (US Patent No. 6,455,090)

Uzuhashi discloses a liquid additive thickener/liquid thickening agent including a liquid that is prepared by dissolving a thickening agent into water (Abstract). The thickening agent is dissolved in a liquid in such a way that the liquid thickener retains its fluidity on mixing. (Col. 1, ll. 63-65). *Uzuhashi* notes that consumers have come to have various preferences that require fresh hand-made foods with strictly selected materials rather than ready-made commodities that are mass produced as processed foods. (Col 2, ll. 45-51). The liquid thickening substance may be utilized in training and nursing facilities to alter the viscosity of food substances for persons with mastication and deglutition difficulties (Cols. 2-3, bridging paragraph). "For such use, it is preferable that the liquid additive thickener is separated little by little and contained individually either in a portion container or a small bag." (Col. 7, ll. 23-26) Possible thickening agents include guar gum, locust bean gum, xanthan gum, sodium carboxymethylcellulose, and carrageenan (Col. 3, ll. 31-37). The thickening agents are prepared as a liquid with a low viscosity that enables it to be dissolved

in water (Col. 3, ll. 38-40). Figure 2 discloses a liquid thickening agent that comprises xanthan gum. *Uzuhashi* notes that the liquid thickening agent of xanthan gum may be dissolved in milk, consomme soup, salad dressing, and many other items (Col. 5, ll. 15-21). *Uzuhashi* describes a number of examples in which different amounts of various thickeners are mixed with a selection of liquid foods. (*see generally*, Cols 4-6).

b. Ascertaining the differences between the prior art and the claims at issue.

"It is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art". *In re Wesslau*, 147 USPQ 391, 353 F.2d 238 (CCPA 1965). Moreover, a prior art reference should not be taken out of context and relied upon with the benefit of hindsight to show obviousness. Rather, a reference should be considered as a whole, and portions arguing against or teaching away from the claimed invention must be considered. *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc.*, 230 USPQ 416, 796 F.2d 443 (Fed. Cir. 1986).

The invention as set out in independent Claim 39 requires "connecting a source of aqueous liquid thickener to a dispensing machine that is capable of dispensing non-thickened beverages." As discussed with respect to anticipation, *Wierlo* does not disclose a process for producing a beverage *suitable for consumption by a person suffering from dysphagia*, does not disclose a process

comprising connecting a source of aqueous liquid thickener to a dispensing machine, and does not disclose a process comprising attaching a source of thickener to a dispenser *that is capable of dispensing non-thickened beverages.* Applicant's Admission and *Uzuhashi* both supply the first italicized deficiency, in that they disclose methods of manually producing a single portion of thickened beverage or food. Neither Applicant's Admission nor *Uzuhashi* supplies any of the other italicized deficiencies of *Wierlo*.

c. Resolving the level of ordinary skill in the pertinent art.

There was no finding by the Examiner as to the level of skill in the art. Appellant submits that the person most concerned with preparation of beverages suitable for consumption by a person suffering from dysphagia would be a health care professional or a dietician involved in the care of such patients. Appellant further asserts that regardless of which art is chosen as "the pertinent art", and what level of ordinary skill is chosen, the process as claimed would not have been obvious to that hypothetical person.

The Examiner Has Not Established *Prima Facie* Obviousness

The Examiner has not established a case of *prima facie* obviousness. To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The

teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. MPEP 2143; *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1970). The references must be considered as a whole, and "[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR Int'l Co. v. Teleflex Inc.*, 550 US 550, 82 USPQ2d 1385, 1396 (2007), quoting with approval *In re Kahn*, 78 USPQ2d 1329, 1336, 441 F.3d 977, 988 (Fed. Cir. 2006).

a. Suggestion or motivation

The Examiner's rationale for combining the references is as follows:

... Uzuhashi et al disclose motivation for one to use a dispensing machine. In particular, the document discloses that the viscosity and formulation of gels of food require that the gels be highly flexible commodities rather than uniform commodities. It is required that fresh ***hand-made*** foods with strictly selected materials rather than ready-made commodities that are mass produced as processed foods be generated. In addition, it is disclosed that the gel may be used to impart preferable viscosity of a ***hand-made dressing***, for example, so as to adhere to vegetables. Imparting viscosity in sauces for meat and fish dishes, adjusting viscosity of a ***liquid starch*** dressing, and imparting viscosity on a fruit sauce are other examples of items that may have an adjusted viscosity. Further, Uzuhashi et al disclose that the liquid active thickener may be utilized in nursing and training facility (see column 2, lines 38-65 and columns 2-3, bridging paragraph). Therefore, since both the thickener and a dispensing machine connected a thickener are well known in the art, one would be motivated to combine the inventions in order to address the issues set forth by Uzuhashi et al. Specifically, Uzuhashi et al discloses why one would be motivated to generate meals made based on an individual's need (i.e., a person in a nursing or training facility having mastication and deglutition difficulties). Thus, Applicant's admission that the thickener is known and the motivation of Uzuhashi et al to have individualized meals, in combination with a dispensing agent of

Wierlo connected to a thickened beverage that may be made to an individual's liking, the skilled artisan would recognize that it is obvious to generate a process of producing a thickened beverage comprising connecting an aqueous liquid thickener to a dispensing machine. Since all of the documents are directed to thickened substances, the references may be considered to be within the same field of endeavor. Thus the reference teachings are combinable.

(February 2, 2010 Final Office Action, pp. 10-12) (emphasis added).

Contrary to the Examiner's assertion, the emphasized phrases in the quoted passage of the rejection show that one skilled in the art following the teachings of *Uzuhashi* would expect that thickened foods must be *hand-made* and not prepared in a dispenser by a process such as Appellant's. Thus, to the extent that *Uzuhashi* teaches anything relevant to the present claims, *Uzuhashi* actually teaches away from Appellant's process, and nothing in Applicant's Admission (individual packets of thickener concentrate) or *Wierlo* suggests otherwise.

Uzuhashi is in fact silent with regard to the process one would use to produce such thickened foods, saying only that the liquid additive thickener is "added" (col. 1, ll. 65-67) or "mixed" (col. 8, ll. 42-44) with an aqueous liquid or aqueous liquid solid mixture. The foods identified by the Examiner as typical of those disclosed by *Uzuhashi* are particularly inappropriate to be dispensed by a dispensing machine capable of dispensing unthickened beverages. Additionally, although the disclosure of *Wierlo* is directed to a dispensing machine, *Wierlo* does not provide the slightest suggestion or motivation to modify a dispensing machine in the manner disclosed and claimed by Appellant. Thus, there is no

suggestion or motivation to combine the cited references to provide the process of Claims 39-45.

b. Reasonable expectation of success

For all of the foregoing reasons, one skilled in the art would have no reasonable expectation that modifying the dispensing machine of *Wierlo* in view of Applicant's Admission and *Uzuhashi* would successfully produce Appellant's novel process. Contrary to the Examiner's assertion that the motivation of *Uzuhashi* et al to have individualized meals, in combination with a dispensing machine of *Wierlo* connected to a thickened beverage that may be made to an individual's liking, without Appellant's disclosure, a skilled artisan would have no expectation, much less a reasonable expectation, that connecting an aqueous liquid thickener to a dispensing machine capable of producing a non-thickened beverage would successfully produce Appellant's novel process.

c. Disclose or suggest all of the claim elements

The references, alone or in combination, do not teach or suggest all of the claim limitations of Claim 39. Nothing in Applicant's Admission or *Uzuhashi* supplies the limitations not disclosed by *Wierlo*. Thus, the cited references do not render Claim 39 obvious.

Although Appellant has admitted individual serving-sized packets of its thickener were in public use more than one year prior to the filing of this application, the cited references, as set out above, *Wierlo* and *Uzuhashi*, do not teach or suggest all the limitations of Claim 39, and hence cannot teach or suggest all the limitations of the dependent claims. The Examiner cannot show

prima facia obviousness. *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1970). The combination of references does not teach or suggest the use of Appellant's thickener in conjunction with Appellant's novel process as specified by the claims.

Claims 40-45 depend from Claim 39, and those claims are also not rendered obvious by the cited references for at least the same reasons as Claim 39. The patentability under 35 U.S.C. 103 of claims 42-45 is not argued separately. Claims 40 and 41 are also not obvious for the reasons set out below.

Claim 40

As discussed above with respect to the rejection under 35 U.S.C. 102, *Wierlo* lacks a number of the elements of the process of claim 40. He does not have a container of thickener concentrate, he does not have a switch which selectively controls whether or not the thickener concentrate is included in the beverage, he does not have a metering pump, and he does not produce beverages which are ready to drink, whether the beverage thickness is increased by the inclusion of the thickener concentrate or not. Nothing in *Wierlo*, *Uzuhashi*, or Applicant's Admission discloses or suggests these elements in any way, whether taken alone or in combination.

Claim 41

As discussed above with respect to the rejection under 35 U.S.C. 102, *Wierlo* lacks a number of the elements of the process of claim 41. He does not have a container of thickener concentrate, he does not have a switch which selectively controls whether or not the thickener concentrate is included in the

beverage, he does not have a metering pump, and he does not produce beverages which are ready to drink, whether the beverage thickness is increased by the inclusion of the thickener concentrate or not. Nothing in *Wierlo, Uzuhashi*, or Applicant's Admission discloses or suggests these elements in any way, whether taken alone or in combination.

Conclusion

Appellant has made an elegantly simple invention. The simplicity of the invention does not indicate obviousness, and in fact "the simplicity of new inventions is oftentimes the very thing that is not obvious before they are made."

In re Sporck, 301 F.2d 686, 133 U.S.P.Q. 360, 363 (CCPA, 1962).

The Examiner has failed to establish that Claims 39-45, all of the claims under examination, are properly rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement, are properly rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Appellant regards as the invention or are unpatentable as obvious under 35 U.S.C. § 103(a) over Applicant's Admission in view of *Wierlo* in further view of *Uzuhashi*. The Examiner has failed to establish that Claims 39-41 are anticipated by *Wierlo* under 35 U.S.C. § 102(b). Appellant has met his burden of establishing that the Examiner erred in making the rejections. Appellant respectfully requests that these rejections of Claims 39-45 be reversed.

Date: August 30, 2010

Respectfully submitted,

/jphilippolster/

J. Philip Polster, Reg. No. 24,739
Polster, Lieder, Woodruff & Lucchesi, LC
12412 Powerscourt Dr., Suite 200
St. Louis, Missouri 63131
Tel: (314) 238-2400
Fax: (314) 238-2401

VIII. CLAIMS APPENDIX (37 C.F.R. §41.37(c)(1)(viii))

39. A process for the production of homogenous single phase thickened beverages suitable for consumption by a person suffering from dysphagia, the process comprising connecting a source of aqueous liquid thickener to a dispensing machine that is capable of dispensing non-thickened beverages.

40. A process in accordance with Claim 39 wherein the dispensing machine includes a container of thickener concentrate, a switch which selectively controls whether or not the thickener concentrate is included in the beverage, and a metering pump and an in-line static mixer connected to the container of thickener concentrate and designed such that beverages exit the dispenser at the correct thickness, with a homogenous appearance and are ready to drink, whether the beverage thickness is increased by inclusion of the thickener concentrate or not.

41. A process in accordance with Claim 39 wherein the dispensing machine includes a container of thickener concentrate, a switch which selectively controls whether or not the thickener concentrate is included in the beverage, a metering pump, and an exit nozzle, the exit nozzle producing a sufficient pressure drop that beverages exit the dispenser at the correct thickness, with a homogenous appearance and are ready to drink, whether the beverage thickness is increased by inclusion of the thickener concentrate or not.

42. A process in accordance with Claim 39 wherein the thickener comprises at least one soluble food fiber thickener selected from the group consisting of

sodium alginate, potassium alginate, ammonium alginate, carrageenan, sodium carboxymethylcellulose, hydroxypropyl cellulose, hydroxypropyl methyl cellulose, locust bean gum, guar gum, and xanthan gum.

43. A process in accordance with Claim 42 where the thickener is xanthan gum.
44. A process in accordance with Claim 42 where the xanthan gum is between 1% and 10% of the thickener concentrate.
45. A process in accordance with Claim 42 where the xanthan gum is between 0.3% and 1% of the beverage.

IX. EVIDENCE APPENDIX

None

X. RELATED PROCEEDINGS APPENDIX
None